



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :  A61L 2/00		A2	(11) International Publication Number: <b>WO 98/58682</b>
			(43) International Publication Date: 30 December 1998 (30.12.98)
<p>(21) International Application Number: PCT/US98/13001</p> <p>(22) International Filing Date: 23 June 1998 (23.06.98)</p> <p>(30) Priority Data: 08/882,466 25 June 1997 (25.06.97) US</p> <p>(71) Applicant: STERIS CORPORATION [US/US]; 5960 Heisley Road, Mentor, OH 44060 (US).</p> <p>(72) Inventor: MACHESKY, Paul, S.; 239 Barrington Ridge, Painesville Twp., OH 44077 (US).</p> <p>(74) Agent: KOCOVSKY, Thomas, E., Jr.; Fay, Sharpe, Beall, Fagan, Minnich &amp; McKee, Suite 700, 1100 Superior Avenue, Cleveland, OH 44114-2518 (US).</p>			<p>(81) Designated States: AU, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: APPARATUS AND METHOD FOR STERILIZING MEDICAL DEVICES</p> <p>(57) Abstract</p> <p>A decontamination apparatus for medical devices includes a decontamination basin (14a, 14b) with a selectively opened and closed cover member (16a, 16b) to provide selective access to the basin (14a, 14b). A mixing chamber assembly (80) selectively dispenses detergent concentrate and decontaminant concentrate into a liquid to form a liquid cleaning solution or a liquid decontaminant solution, respectively. A source of decontaminated rinse liquid, such as a microbe removal filter (54), is in selective fluid communication with the basin (14a, 14b). A source of anti-microbial liquid is in selective fluid communication with the microbe removal filter (54) and rinse liquid flow paths (58) between the microbe removal filter and the basin for decontaminating the filter (54) and the rinse lines (58). Each channel of a medical device (E) being decontaminated is connected to a channel flush line (30) and a channel pump (32) for flushing the channels of the device (E). A pressure sensor (42) is in communication with each flush line (30) to sense a blockage in the channels of the medical device (E). The channel pumps (32) pump liquid or decontaminated air through the device channels. A leak test system is also provided for testing the integrity of an outer sheath of a medical device (E) such as an endoscope.</p> <img alt="Schematic diagram of the apparatus for sterilizing medical devices. The diagram shows a central mixing chamber assembly (80) connected to various fluid lines. A decontamination basin (14a, 14b) is shown with a cover member (16a, 16b). A microbe removal filter (54) is connected to the basin. A channel pump (32) and flush line (30) are connected to a medical device (E). A pressure sensor (42) is connected to the flush line (30). A leak test system is also shown. Various valves (110, 114, 116, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 190, 192, 194, 196, 198, 200, 202, 204, 206, 208, 210, 212, 214, 216, 218, 220, 222, 224, 226, 228, 230, 232, 234, 236, 238, 240, 242, 244, 246, 248, 250, 252, 254, 256, 258, 260, 262, 264, 266, 268, 270, 272, 274, 276, 278, 280, 282, 284, 286, 288, 290, 292, 294, 296, 298, 300, 302, 304, 306, 308, 310, 312, 314, 316, 318, 320, 322, 324, 326, 328, 330, 332, 334, 336, 338, 340, 342, 344, 346, 348, 350, 352, 354, 356, 358, 360, 362, 364, 366, 368, 370, 372, 374, 376, 378, 380, 382, 384, 386, 388, 390, 392, 394, 396, 398, 400, 402, 404, 406, 408, 410, 412, 414, 416, 418, 420, 422, 424, 426, 428, 430, 432, 434, 436, 438, 440, 442, 444, 446, 448, 450, 452, 454, 456, 458, 460, 462, 464, 466, 468, 470, 472, 474, 476, 478, 480, 482, 484, 486, 488, 490, 492, 494, 496, 498, 500, 502, 504, 506, 508, 510, 512, 514, 516, 518, 520, 522, 524, 526, 528, 530, 532, 534, 536, 538, 540, 542, 544, 546, 548, 550, 552, 554, 556, 558, 560, 562, 564, 566, 568, 570, 572, 574, 576, 578, 580, 582, 584, 586, 588, 590, 592, 594, 596, 598, 600, 602, 604, 606, 608, 610, 612, 614, 616, 618, 620, 622, 624, 626, 628, 630, 632, 634, 636, 638, 640, 642, 644, 646, 648, 650, 652, 654, 656, 658, 660, 662, 664, 666, 668, 670, 672, 674, 676, 678, 680, 682, 684, 686, 688, 690, 692, 694, 696, 698, 700, 702, 704, 706, 708, 710, 712, 714, 716, 718, 720, 722, 724, 726, 728, 730, 732, 734, 736, 738, 740, 742, 744, 746, 748, 750, 752, 754, 756, 758, 760, 762, 764, 766, 768, 770, 772, 774, 776, 778, 780, 782, 784, 786, 788, 790, 792, 794, 796, 798, 800, 802, 804, 806, 808, 810, 812, 814, 816, 818, 820, 822, 824, 826, 828, 830, 832, 834, 836, 838, 840, 842, 844, 846, 848, 850, 852, 854, 856, 858, 860, 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 894, 896, 898, 900, 902, 904, 906, 908, 910, 912, 914, 916, 918, 920, 922, 924, 926, 928, 930, 932, 934, 936, 938, 940, 942, 944, 946, 948, 950, 952, 954, 956, 958, 960, 962, 964, 966, 968, 970, 972, 974, 976, 978, 980, 982, 984, 986, 988, 990, 992, 994, 996, 998, 999, 1000, 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, 1009, 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1024, 1025, 1026, 1027, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1035, 1036, 1037, 1038, 1039, 1040, 1041, 1042, 1043, 1044, 1045, 1046, 1047, 1048, 1049, 1050, 1051, 1052, 1053, 1054, 1055, 1056, 1057, 1058, 1059, 1060, 1061, 1062, 1063, 1064, 1065, 1066, 1067, 1068, 1069, 1070, 1071, 1072, 1073, 1074, 1075, 1076, 1077, 1078, 1079, 1080, 1081, 1082, 1083, 1084, 1085, 1086, 1087, 1088, 1089, 1090, 1091, 1092, 1093, 1094, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 1111, 1112, 1113, 1114, 1115, 1116, 1117, 1118, 1119, 1120, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1133, 1134, 1135, 1136, 1137, 1138, 1139, 1140, 1141, 1142, 1143, 1144, 1145, 1146, 1147, 1148, 1149, 1150, 1151, 1152, 1153, 1154, 1155, 1156, 1157, 1158, 1159, 1160, 1161, 1162, 1163, 1164, 1165, 1166, 1167, 1168, 1169, 1170, 1171, 1172, 1173, 1174, 1175, 1176, 1177, 1178, 1179, 1180, 1181, 1182, 1183, 1184, 1185, 1186, 1187, 1188, 1189, 1190, 1191, 1192, 1193, 1194, 1195, 1196, 1197, 1198, 1199, 1200, 1201, 1202, 1203, 1204, 1205, 1206, 1207, 1208, 1209, 1210, 1211, 1212, 1213, 1214, 1215, 1216, 1217, 1218, 1219, 1220, 1221, 1222, 1223, 1224, 1225, 1226, 1227, 1228, 1229, 1230, 1231, 1232, 1233, 1234, 1235, 1236, 1237, 1238, 1239, 12310, 12311, 12312, 12313, 12314, 12315, 12316, 12317, 12318, 12319, 12320, 12321, 12322, 12323, 12324, 12325, 12326, 12327, 12328, 12329, 12330, 12331, 12332, 12333, 12334, 12335, 12336, 12337, 12338, 12339, 12340, 12341, 12342, 12343, 12344, 12345, 12346, 12347, 12348, 12349, 12350, 12351, 12352, 12353, 12354, 12355, 12356, 12357, 12358, 12359, 12360, 12361, 12362, 12363, 12364, 12365, 12366, 12367, 12368, 12369, 12370, 12371, 12372, 12373, 12374, 12375, 12376, 12377, 12378, 12379, 12380, 12381, 12382, 12383, 12384, 12385, 12386, 12387, 12388, 12389, 12390, 12391, 12392, 12393, 12394, 12395, 12396, 12397, 12398, 12399, 123100, 123101, 123102, 123103, 123104, 123105, 123106, 123107, 123108, 123109, 123110, 123111, 123112, 123113, 123114, 123115, 123116, 123117, 123118, 123119, 123120, 123121, 123122, 123123, 123124, 123125, 123126, 123127, 123128, 123129, 123130, 123131, 123132, 123133, 123134, 123135, 123136, 123137, 123138, 123139, 123140, 123141, 123142, 123143, 123144, 123145, 123146, 123147, 123148, 123149, 123150, 123151, 123152, 123153, 123154, 123155, 123156, 123157, 123158, 123159, 123160, 123161, 123162, 123163, 123164, 123165, 123166, 123167, 123168, 123169, 123170, 123171, 123172, 123173, 123174, 123175, 123176, 123177, 123178, 123179, 123180, 123181, 123182, 123183, 123184, 123185, 123186, 123187, 123188, 123189, 123190, 123191, 123192, 123193, 123194, 123195, 123196, 123197, 123198, 123199, 123200, 123201, 123202, 123203, 123204, 123205, 123206, 123207, 123208, 123209, 123210, 123211, 123212, 123213, 123214, 123215, 123216, 123217, 123218, 123219, 123220, 123221, 123222, 123223, 123224, 123225, 123226, 123227, 123228, 123229, 123230, 123231, 123232, 123233, 123234, 123235, 123236, 123237, 123238, 123239, 123240, 123241, 123242, 123243, 123244, 123245, 123246, 123247, 123248, 123249, 123250, 123251, 123252, 123253, 123254, 123255, 123256, 123257, 123258, 123259, 123260, 123261, 123262, 123263, 123264, 123265, 123266, 123267, 123268, 123269, 123270, 123271, 123272, 123273, 123274, 123275, 123276, 123277, 123278, 123279, 123280, 123281, 123282, 123283, 123284, 123285, 123286, 123287, 123288, 123289, 123290, 123291, 123292, 123293, 123294, 123295, 123296, 123297, 123298, 123299, 123300, 123301, 123302, 123303, 123304, 123305, 123306, 123307, 123308, 123309, 123310, 123311, 123312, 123313, 123314, 123315, 123316, 123317, 123318, 123319, 123320, 123321, 123322, 123323, 123324, 123325, 123326, 123327, 123328, 123329, 123330, 123331, 123332, 123333, 123334, 123335, 123336, 123337, 123338, 123339, 123340, 123341, 123342, 123343, 123344, 123345, 123346, 123347, 123348, 123349, 123350, 123351, 123352, 123353, 123354, 123355, 123356, 123357, 123358, 123359, 123360, 123361, 123362, 123363, 123364, 123365, 123366, 123367, 123368, 123369, 123370, 123371, 123372, 123373, 123374, 123375, 123376, 123377, 123378, 123379, 123380, 123381, 123382, 123383, 123384, 123385, 123386, 123387, 123388, 123389, 123390, 123391, 123392, 123393, 123394, 123395, 123396, 123397, 123398, 123399, 123400, 123401, 123402, 123403, 123404, 123405, 123406, 123407, 123408, 123409, 123410, 123411, 123412, 123413, 123414, 123415, 123416, 123417, 123418, 123419, 123420, 123421, 123422, 123423, 123424, 123425, 123426, 123427, 123428, 123429, 123430, 123431, 123432, 123433, 123434, 123435, 123436, 123437, 123438, 123439, 123440, 123441, 123442, 123443, 123444, 123445, 123446, 123447, 123448, 123449, 123450, 123451, 123452, 123453, 123454, 123455, 123456, 123457, 123458, 123459, 123460, 123461, 123462, 123463, 123464, 123465, 123466, 123467, 123468, 123469, 123470, 123471, 123472, 123473, 123474, 123475, 123476, 123477, 123478, 123479, 123480, 123481, 123482, 123483, 123484, 123485, 123486, 123487, 123488, 123489, 123490, 123491, 123492, 123493, 123494, 123495, 123496, 123497, 123498, 123499, 123500, 123501, 123502, 123503, 123504, 123505, 123506, 123507, 123508, 123509, 123510, 123511, 123512, 123513, 123514, 123515, 123516, 123517, 123518, 123519, 123520, 123521, 123522, 123523, 123524, 123525, 123526, 123527, 123528, 123529, 123530, 123531, 123532, 123533, 123534, 123535, 123536, 123537, 123538, 123539, 123540, 123541, 123542, 123543, 123544, 123545, 123546, 123547, 123548, 123549, 123550, 123551, 123552, 123553, 123554, 123555, 123556, 123557, 123558, 123559, 123560, 123561, 123562, 123563, 123564, 123565, 123566, 123567, 123568, 123569, 123570, 123571, 123572, 123573, 123574, 123575, 123576, 123577, 123578, 123579, 123580, 123581, 123582, 123583, 123584, 123585, 123586, 123587, 123588, 123589, 123590, 123591, 123592, 123593, 123594, 123595, 123596, 123597, 123598, 123599, 123600, 123601, 123602, 123603, 123604, 123605, 123606, 123607, 123608, 123609, 123610, 123611, 123612, 123613, 123614, 123615, 123616, 123617, 123618, 123619, 123620, 123621, 123622, 123623, 123624, 123625, 123626, 123627, 123628, 123629, 123630, 123631, 123632, 123633, 123634, 123635, 123636, 123637, 123638, 123639, 123640, 123641, 123642, 123643, 123644, 123645, 123646, 123647, 123648, 123649, 123650, 123651, 123652, 123653, 123654, 123655, 123656, 123657, 123658, 123659, 123660, 123661, 123662, 123663, 123664, 123665, 123666, 123667, 123668, 123669, 123670, 123671, 123672, 123673, 123674, 123675, 123676, 123677, 123678, 123679, 123680, 123681, 123682, 123683, 123684, 123685, 123686, 123687, 123688, 123689, 123690, 123691, 123692, 123693, 123694, 123695, 123696, 123697, 123698, 123699, 123700, 123701, 123702, 123703, 123704, 123705, 123706, 123707, 123708, 123709, 123710, 123711, 123712, 123713, 123714, 123715, 123716, 123717, 123718, 123719, 123720, 123721, 123722, 123723, 123724, 123725, 123726, 123727, 123728, 123729, 123730, 123731, 123732, 123733, 123734, 123735, 123736, 123737, 123738, 123739, 123740, 123741, 123742, 123743, 123744, 123745, 123746, 123747, 123748, 123749, 123750, 123751, 123752, 123753, 123754, 123755, 123756, 123757, 123758, 123759, 123760, 123761, 123762, 123763, 123764, 123765, 123766, 123767, 123768, 123769, 123770, 123771, 123772, 123773, 123774, 123775, 123776, 123777, 123778, 123779, 123780, 123781, 123782, 123783, 123784, 123785, 123786, 123787, 123788, 123789, 123790, 123791, 123792, 123793, 123794, 123795, 123796, 123797, 123798, 123799, 123800, 123801, 123802, 123803, 123804, 123805, 123806, 123807, 123808, 123809, 123810, 123811, 123812, 123813, 123814, 123815, 123816, 123817, 123818, 123819, 123820, 123821, 123822, 123823, 123824, 123825, 123826, 123827, 123828, 123829, 123830, 123831,			

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## APPARATUS AND METHOD FOR STERILIZING MEDICAL DEVICES

Background of the Invention

The present invention relates to the decontamination arts including the sterilization arts. It finds particular application in conjunction with the decontamination of medical devices, especially medical devices such as endoscopes and other devices having channels or lumens that must be decontaminated after use.

Sterilization is typically defined as the absence of all life forms including bacterial endospores which are the living organisms most resistant to known sterilants. Disinfection, by distinction, only connotes the absence of pathogenic life forms. Herein, the general term, decontamination, will be used to describe both disinfection and sterilization.

Endoscopes and similar medical devices having channels or lumens formed therethrough are being used on an ever increasing basis in the performance of medical procedures. The popularity of these devices has led to calls for improvements in the decontamination of these devices between use, both in terms of the speed of the decontamination and the effectiveness of the decontamination. One drawback associated with many known endoscope decontamination devices is their reliance on reusable glutaraldehyde or the like as a liquid decontaminant solution. While glutaraldehyde is generally effective for disinfection, sterilization with glutaraldehyde can take 10 to 12 hours which is too long in today's healthcare facilities. Another drawback to glutaraldehyde systems is that they sterilize without cleaning, i.e., they leave sterile biological waste matter on the medical instruments.

-2-

Another drawback associated with many known decontamination devices is their lack of a decontaminated rinse liquid. Many known decontamination devices are concerned only with cleaning and disinfecting the devices 5 and consequently rely on unfiltered "tap" water for rinsing. Even those that filter or otherwise decontaminate the rinse liquid often do not decontaminate the rinse liquid flow paths between the source of rinse liquid and the decontamination basin under the incorrect 10 assumption that these apparently closed rinse liquid flow paths cannot become contaminated. Thus, with these devices, it is possible for microorganisms to be reintroduced onto the medical device from the rinse liquid. One known endoscope sterilizer does provide a 15 sterile rinse and rinse liquid flow path (STERIS SYSTEM 1™, STERIS Corporation, Mentor, Ohio). However, it would be desirable to include additional features in conjunction with the sterile rinse and sterile rinse flow paths of this unit.

20 Prior medical instrument decontamination devices do not include a simple and effective means for accurately delivering a select charge of both detergent concentrate and decontaminant concentrate as needed to form a cleaning solution and a decontamination solution, 25 respectively. Instead, many prior devices rely upon a large tank to hold a reusable decontaminant such as glutaraldehyde and rely upon tank of detergent that must be refilled. The need to refill these tanks periodically decreases efficiency and also puts an operator in contact 30 with decontaminant and detergent liquid and vapors. Further, glutaraldehyde is an environmentally hazardous material that needs to be chemically deactivated. Disposal or reprocessing of diluted or contaminated glutaraldehyde is inconvenient and costly.

35 Furthermore, with these systems, it is possible

-3-

for the detergent tank or the decontaminant tank to run dry without the knowledge of the machine operator. Also, it is not always possible to verify that the detergent or decontaminant has actually been properly and accurately dispensed into the decontamination basin. It would be desirable to provide a decontamination apparatus that simply and accurately dispenses a select dose of detergent concentrate and decontaminant concentrate as needed, without requiring tanks to be refilled and without exposing an operator to detergents and decontaminants. It would also be desirable to provide such a system which reduces the possibility that an incorrect amount of detergent or decontaminant will be dispensed.

The present application is therefore directed to a method and apparatus which overcomes these problems and others while providing better overall decontamination results and efficiency.

#### Summary of the Invention

In accordance with one aspect of the present invention, an apparatus for cleaning and microbially decontaminating a medical device having at least one internal channel formed therein includes a decontamination area for receiving a non-sterile device and at least one pump having an inlet in fluid communication with the decontamination area and an outlet for connection with the at least one internal channel of the device such that liquid from the decontamination area is circulated through the at least one internal channel by the at least one pump. At least one spray nozzle is positioned in the decontamination area and is fluidically connected to the at least one pump to spray liquid onto exterior surfaces of the device in the decontamination area. A source of sterile rinse liquid includes a

- 4 -

microbe removal filter and rinse liquid pathways in selective fluid communication with the pump so that liquid microbial decontaminant is selectively communicated from the decontamination area into the 5 microbe removal filter and through the rinse liquid pathways to microbially decontaminate the filter and the pathways. The apparatus further includes a mixing chamber for sequentially dispensing (i) a detergent concentrate and, thereafter (ii) a microbial 10 decontamination concentrate into liquid passing through the mixing chamber. The mixing chamber is adapted to receive a multi-compartment ampule including a first interior compartment holding a charge of detergent concentrate and at least a second interior compartment 15 holding a charge of microbial decontamination concentrate. A means is provided for sequentially opening the first interior compartment of the ampule to release the charge of detergent concentrate and, thereafter, the at least one second interior compartment 20 of the ampule to release the charge of decontaminant concentrate. An electronic control means is operatively connected to and controls the ampule opening means to open the first interior compartment during a cleaning cycle of the apparatus and to open the second interior 25 compartment during a microbial decontamination cycle of the apparatus.

In accordance with another aspect of the invention, a method of cleaning and sterilizing the exterior surfaces and interior channels of a medical 30 device includes placing the device in a receiving area, circulating a cleaning solution over the exterior surfaces and through the internal channels of the device, and draining cleaning solution from the device receiving area. A rinse liquid is circulated over the exterior 35 surfaces and through the internal channels of the device

-5-

in the receiving area and is drained from the device receiving area. Internal channels of the device are flushed with air to remove residual liquid from the channels in the device. The method further includes 5 circulating liquid sterilant over the exterior surfaces and through the internal channels of the device in the device receiving area, circulating the liquid sterilant into a rinse water microbe removal filter and through rinse liquid pathways between the microbe removal filter and the device receiving area to sterilize the filter and 10 pathways, and draining the liquid sterilant from the device receiving area. A rinse water is passed through the microbe removal filter to sterilize the rinse water and the sterile rinse water is communicated through only 15 the previously sterilized rinse liquid pathways to the device receiving area. The sterile rinse water is circulated over the exterior surfaces and through the internal channels of the device in the receiving area, and drained from the device receiving area. The cleaning 20 solution is formed by mixing detergent concentrate with water by opening a first compartment of a multi-compartment container that contains detergent concentrate to dispense the detergent concentrate in the water. The liquid sterilant is formed by mixing sterilant 25 concentrate with water by opening at least a second compartment of the multi-compartment container that contains sterilant concentrate to dispense the sterilant concentrate into the water.

One advantage of the present invention is that 30 it provides an improved decontamination apparatus and method.

Another advantage of the present invention is that it provides for accurately and conveniently dispensing detergent and decontaminant concentrate 35 ingredients into a liquid to form a cleaning solution or

-6-

a decontamination solution.

Still another advantage of the present invention resides in the use of a single-use decontaminant.

5 A further advantage of the present invention is that it provides a decontaminated rinse liquid and decontaminated rinse liquid flow paths for communicating the decontaminated rinse liquid onto and through the channels of the decontaminated medical device.

10 A further advantage of the present invention resides in its provision of a leak test system for testing the integrity of a sheath or housing forming a part of an endoscope or other device being decontaminated.

15 A further advantage of the present invention is that it allows each interior flow channel of a medical device to be individually flushed with liquid or decontaminated air and that each interior channel of the medical device can be monitored for blockage.

20 Yet another advantage of the present invention is the provision of a "break tank" water supply system for isolating the apparatus from a utility or "tap" water supply system.

25 still further advantages of the present invention will become apparent to those of ordinary skill in the art upon their reading and understanding of the following specification of the preferred embodiments.

#### Brief Description of the Drawings

30 The invention may take form in various components and arrangements of components and in various steps and arrangements of steps. The drawings are for purposes of illustrating preferred embodiments only, and are not to be construed as limiting the invention.

FIGURE 1 is a front elevational view of a

- 7 -

decontamination apparatus in accordance with the present invention;

5 FIGURE 2 is a diagrammatic illustration of the decontamination apparatus shown in FIGURE 1, with only a single decontamination basin shown for clarity; and,

FIGURE 3 is an exploded view of a detergent and decontaminant concentrate delivery system in accordance with the present invention.

Detailed Description of the Preferred Embodiment

10 FIGURE 1 shows a decontamination apparatus for decontaminating endoscopes and other medical devices which include channels or lumens formed therethrough. The decontamination apparatus generally includes a first station 10 and a second station 12 which are at least 15 substantially similar in all respects to provide for the decontamination of two different medical devices simultaneously or in series. First and second decontamination basins 14a,14b receive the contaminated devices. Each basin 14a,14b is selectively sealed by a 20 lid 16a,16b, respectively, preferably in a microbe-blocking relationship to prevent the entrance of environmental microbes into the basins 14a,14b during decontamination operations. The lids can include a microbe removal or HEPA air filter formed therein for 25 venting.

A control system 20 includes one or more microcontrollers, such as a programmable logic controller (PLC), for controlling decontamination and user interface operations. Although one control system is shown herein 30 as controlling both decontamination stations 10,12, those skilled in the art will recognize that each station 10,12 can include a dedicated control system. A visual display 22 displays decontamination parameters and machine conditions for an operator and at least one printer 24

-8-

prints a hard copy output of the decontamination parameters for a record to be filed or attached to the decontaminated device or its storage packaging. The visual display 22 is preferably combined with a touch screen input device. Alternatively, a keypad or the like is provided for input of decontamination process parameters and for machine control. Other visual gauges 26 such as pressure meters and the like provide digital or analog output of decontamination or medical device leak testing data.

FIGURE 2 diagrammatically illustrates one station 10 of the decontamination apparatus. Those skilled in the art will recognize that the decontamination station 12 is preferably similar in all respects to the station 10 illustrated in FIGURE 2. However, the station 12 has not been shown in FIGURE 2 for clarity. Further, the decontamination apparatus can be provided with a single decontamination station or multiple stations.

The decontamination basin 14a receives an endoscope E or other medical device therein for decontamination. Any internal channels of the medical device E are connected with flush lines 30. Each flush line 30 is connected to an outlet of a pump 32. The pumps 32 are preferably peristaltic pumps or the like that pump fluid, such as liquid and air, through the flush lines 30 and any internal channels of the medical device E. Specifically, the pumps 32 can either draw liquid from the basin 14a through a drain 34 and a first valve 81, or can draw decontaminated air from an air supply system 36 through a valve 82. The air supply system 36 includes a pump 38 and a microbe removal air filter 40 that filters microbes from an incoming air stream. It is preferable that each flush line 30 be provided with a dedicated pump 32 to ensure adequate

-9-

fluid pressure and to facilitate the individual monitoring of the fluid pressure in each flush line 30. A pressure switch or sensor 42 is in fluid communication with each flush line 30 for sensing excessive pressure in the flush line. Any excessive pressure sensed is indicative of a partial or complete blockage, e.g., by bodily tissue or dried bodily fluids, in a device channel to which the relevant flush line 30 is connected. The isolation of each flush line 30 relative to the others allows the particular blocked channel to be easily identified and isolated, depending upon which sensor 42 senses excessive pressure.

The basin 14a is in fluid communication with a water source 50 such as a utility or "tap" water connection. A pump is optionally provided to boost the pressure of the water from the utility water connection 50. Alternatively, a "break tank" 52 and an associated pump P provide a source a water which is isolated from the utility connection 50 as is required in certain applications. A valve S3 selectively blocks the flow of utility water into the basin 14a from the source 50. A microbe removal filter 54, such as a 0.2 $\mu$ m or smaller absolute pore size filter, decontaminates the incoming water which is delivered into the basin through a faucet fixture 56 or the like. A valve S4 selectively allows the decontaminated water to flow through a rotating spray nozzle assembly 60 to spray decontaminated rinse water into the basin 14a and onto the medical device E. The condition of the filter 54 can be monitored by directly monitoring the flow rate of water therethrough or indirectly by monitoring the basin fill time using a float switch or the like. When the flow rate drops below a select threshold, this indicates a partially clogged filter element that requires replacement.

35 A basin drain 62 drains liquid from the basin

-10-

14a. The drain 62 can include an enlarged helical tube 64 into which elongated portions of the medical device E can be inserted if needed to ensure that the device can be accommodated in the basin 14a. The drain 62 is in 5 fluid communication with a recirculation pump 70 and a drain pump 72. The recirculation pump 70 recirculates liquid from the basin drain 62 to the spray nozzle assembly 60 or otherwise back to the basin to contact the medical device E. The drain pump 72 pumps liquid from 10 the basin drain 62 to a utility drain 74. A flow switch 76 monitors the flow of liquid from the pump 72 to the utility drain 74. The pumps 70,72 can be simultaneously operated such that liquid is sprayed into the basin 14a while it is being drained to encourage the flow of 15 residue out of the basin and off of the device. Likewise, the valves S3 and S4 can be opened while the pump 72 operates to spray decontaminated rinse water into the basin 14a and onto the medical device E during 20 draining operations to provide a better draining of decontaminant or cleaning fluid residue. Of course, a single pump and a valve assembly could replace the dual pumps 70,72.

A mixing chamber assembly 80 includes an inlet 82 in fluid communication with an outlet of the 25 recirculation pump 70. An outlet 84 of the mixing chamber assembly 80 communicates with the spray nozzle assembly 60 through a heating element 86 which selectively heats liquid passing therethrough. A pressure switch or sensor 88 monitors the fluid pressure 30 between the mixing chamber assembly 80 and the spray nozzle assembly 60.

With reference now also to FIGURE 3, the mixing chamber assembly 80 includes an ampule receiving chamber 90 that receives an ampule A or an equivalent container. 35 The chamber 90 is preferably positioned for easy operator

-11-

access in the top surface of the basin 14a and a means is provided for securing an ampule A in the chamber 90. For example, if the chamber 90 is formed in the top surface of the basin 14a, an inner surface of the lid 16a can be 5 utilized to secure an ampule in the chamber 90 when the lid 16a is closed.

The ampule A includes a first interior compartment A1 which contains a detergent concentrate in liquid or dry form. The ampule A also includes second and third interior compartments A2,A3 which contain liquid or dry decontaminant concentrate ingredients. The ampule A is made from a frangible material such as plastic and includes a vented foil, paper, or plastic lid to seal its contents while permitting outgassing. 10 Analogously, releasable panels or other closures can 15 separate and provide selective access to the compartments.

As is indicated by the arrow 92, the ampule A is inserted into the chamber 90. A lance 94 or the like protrudes into the chamber 90 and opens, e.g., pierces, 20 a wall of the first ampule compartment A1 when the ampule is inserted into the chamber 90. In this manner, any water or other liquid flowing through the chamber 90 (indicated by the arrows W) mixes with the detergent 25 concentrate in the compartment A1 to form a liquid cleaning solution. The cleaning solution is optionally heated by the element 86 and is communicated into the decontamination basin 14a through the spray nozzle assembly 60. The liquid cleaning solution is 30 recirculated with the pump 70 through the spray nozzle assembly 60 to clean the exterior of the device E and is recirculated with the pumps 32 to clean any internal channels of the device E. After cleaning, the pump 72 removes the detergent and water mixture. Sterile rinse 35 water sterilized by the filter 54 flushes the detergent

-12-

5 and any contaminants resulting from washing operations out of the system. At this point, the pumps 32 are optionally activated along with the opening of the valve 82 and the operation of the air pump 38 to flush sterile air through all channels of the medical device E. This "air rinse" is useful for removing residual sterile water from the channels of the medical device which could undesirably dilute any sterilant subsequently passed through the channels.

10 In a like manner, the mixing chamber assembly 80 subsequently accesses the second and third interior compartments A2,A3 to introduce decontaminant concentrate ingredients into water, received through the filter 54, in the chamber 90 where the ingredients mix with each 15 other and the water to form liquid decontaminant. A preferred decontamination concentrate is a peracetic acid sterilant concentrate described in U.S. Patent 5,077,008, which is expressly incorporated by reference herein. However, any other suitable decontaminant concentrate can 20 be utilized. The mixing chamber assembly 80 selectively accesses the compartments A2,A3 by advancing the lance 94 further into the chamber 90 (as shown in phantom) to pierce a wall of the compartments A2,A3. An actuator 96, such as one or more solenoids, fluid cylinders, or the 25 like, selectively advances and retracts the lance 94 as indicated by the arrow 98 and optionally rotates the lance 94 as indicated by the arrow 100 to pierce or otherwise access the compartments A2,A3. The decontaminant concentrate in the compartments A2,A3 mixes 30 with clear rinse water or other liquid in the chamber 90 to form a decontaminant solution such as liquid peracetic acid. A seal 8 prevents liquid flow between the outer surface of the lance and the chamber 90.

35 Each time decontaminant concentrate is mixed with water or other liquid in the chamber 90 to form the

-13-

liquid decontaminant, the valve **S4** is preferably opened (while the valve **S3** remains closed), at least for a select duration, so that liquid decontaminant flows into the microbe removal water filter **54** and the conduit **58** decontaminating the rinse liquid flow paths in their entirety from the filter **54** to the basin **14a**. The liquid decontaminant decontaminates the filter **54** and the flow path **58** to ensure that a truly decontaminated rinse liquid is communicated into the basin **14a** and onto the device **E**.

After the decontamination cycle, the pump **72** drains the decontaminant solution and a sterile rinse is again introduced through the filter **54**. Once any decontaminant residue is flushed from the device **E**, the air pump **38** and the pumps **32** are again activated to pump sterile air, sterilized by the filter **40**, through channels in the device **E** to blow out any trapped liquid. Optionally, the sterile air can be used for partially or for fully drying the device.

Endoscopes and other reusable medical devices often include a flexible outer housing or sheath surrounding the individual tubular members and the like that form the interior channels and other parts of the device. This housing defines a closed interior space which is isolated from patient tissues and fluids during medical procedures. It is important that the sheath be maintained intact, without cuts or other holes that would allow contamination of the interior space beneath the sheath. Therefore, the decontamination apparatus includes means for testing the integrity of such as sheath.

An air pump, either the pump **38** or another pump **110**, pressurizes the interior space defined by the sheath of the device through a conduit **112** and a valve **85**. Optionally, a HEPA or other microbe removing filter

-14-

removes microbes from the pressurizing air. An overpressure switch 114 prevents accidental overpressurization of the sheath. Upon full pressurization, the valve S5 is closed and a pressure sensor 116 looks for a drop in pressure in the conduit 112 which would indicate the escape of air through the sheath. A valve S6 selectively vents the conduit 112 and the sheath through an optional filter 118 when the testing procedure is complete.

In addition to the input and output devices described above, all of the electrical and electromechanical devices described are operatively connected to and controlled by the control system 20. Specifically, the switches and sensors 42,76,88,114,116 provide input I to the microcontroller 28 such as a PLC. The PLC 28 receives the input I and controls the decontamination and other machine operations in accordance therewith. For example, the PLC 28 includes outputs O that are operatively connected to the pumps 32,38,54,70,72,110, the valves S1-S6, the mixing chamber assembly actuator 94, and the heating element 86 to control these devices for effective decontamination and other operations.

-15-

Having thus described the preferred embodiments, the invention is now claimed to be:

1. An apparatus for cleaning and microbially decontaminating a medical device having at least one internal channel, said apparatus including a decontamination area (14a) for receiving a non-sterile device (E), at least one pump (32,70) having an inlet in fluid communication with the decontamination area (14a) and an outlet for connection with the at least one internal channel of the device (E) such that liquid from the decontamination area (14a) is circulated through the at least one internal channel by the at least one pump (32,70), at least one spray nozzle (60) positioned in the decontamination area (14a) and fluidically connected to the at least one pump (32,70) to spray liquid onto exterior surfaces of the device (E) in the decontamination area, and a source of sterile rinse liquid including a microbe removal filter (54) and rinse liquid pathways (56), said microbe removal filter (54) and said rinse liquid pathways (56) in selective fluid communication with the at least one pump (32,70) for communicating liquid microbial decontaminant from the decontamination area into the microbe removal filter (54) and through the rinse liquid pathways (56) to microbially decontaminate the filter and the pathways, said apparatus further comprising:
  - 25 a mixing chamber (80) fluidically connected with the pump for receiving a multi-compartment ampule (A) including a first interior compartment (A1) holding a charge of detergent concentrate and at least a second interior compartment (A2) holding a charge of microbial decontamination concentrate;

-16-

35 an ampule opening means (94,96) for sequentially opening (i) the first interior compartment (A1) of the ampule (A) to release the charge of detergent concentrate and, thereafter, (ii) the at least one second interior compartment (A2) of the ampule (A) to release the charge of decontaminant concentrate such that (i) a detergent concentrate and, thereafter (ii) a microbial decontamination concentrate are sequentially dispensed into liquid pumped through the mixing chamber; and,

40 electronic control means (28) operatively connected to and controlling the ampule opening means to open the first interior compartment (A1) during a cleaning cycle of the apparatus and to open the at least one second interior compartment (A2) during a microbial decontamination cycle of the apparatus.

45

2. The cleaning and decontamination apparatus as set forth in claim 1 further comprising:

a source of sterile air (110) in selective fluid communication with the inlet of the at least one pump (32,70) for circulating sterile air through the internal channels of the device (E).

3. The cleaning and decontamination apparatus as set forth in either of claims 1 or 2 wherein said at least one pump comprises:

5 a plurality of channel pumps (32) each having an inlet in fluid communication with the decontamination area (14a) and an outlet adapted for fluid communication with an internal channel of the device (E); and,

10 a recirculation pump (70) having an inlet in fluid communication with the decontamination area (14a) and an outlet in fluid communication with the spray nozzle (60).

-17-

4. The cleaning and decontamination apparatus as set forth in claim 3 further comprising:

a plurality of fluid pressure sensors (42) respectively in fluid communication with the plurality of channel pump outlets for individually and independently sensing fluid pressure at each channel pump outlet.

5. The cleaning and decontamination apparatus as set forth in any of claims 1-4 wherein said ampule compartment opening means further comprises:

5 for opening the first ampule compartment (A1) to dispense the charge of detergent concentrate into a liquid flowing in the mixing chamber (80) and a second position for opening the at least one second ampule compartment (A2) to dispense the charge of decontaminant concentrate into a liquid flowing in the mixing chamber(80); and,

10 an actuator (96) controlled by the electronic control means (28) for selectively moving the plunger (96) between the first and second positions.

6. The cleaning and decontamination apparatus as set forth in any of claims 1-5 comprising:

5 a source of pressurized fluid (110) in selective communication with a sealed interior area of the device in the decontamination area; and,

a fluid pressure monitor (116) connected to the sealed interior area for monitoring pressure of the fluid in the sealed interior area.

7. The cleaning and decontamination apparatus as set forth in any of claims 1-6 wherein said electronic control means monitors a flow rate of water through the microbe removal filter (54) to monitor the condition of the filter.

-18-

8. A method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) including placing the device in a receiving area, circulating a cleaning solution over the exterior surfaces and through the internal channels of the device, circulating an antimicrobial liquid over the exterior surfaces and through the internal channels of the device, circulating the antimicrobial liquid into a rinse water microbe removal filter and through rinse liquid pathways between the microbe removal filter and the device receiving area to kill microbes in the filter and the pathways, passing rinse water through the microbe removal filter to remove microbes from the rinse water and communicating the microbe-free rinse water through only the previously antimicrobial liquid treated rinse liquid pathways to the device receiving area, and circulating the microbe-free rinse water over the exterior surfaces and through the internal channels of the device, the method characterized by:

opening a first compartment (A1) of a multi-compartment container (A) that contains detergent concentrate to dispense the detergent concentrate;

mixing the dispensed detergent concentrate with water to form the cleaning solution and circulating the cleaning solution over the exterior surfaces and through the interior channels of the device (E);

draining the cleaning solution;

opening at least a second compartment (A2) of the multi-compartment container (A) that contains an antimicrobial concentrate to dispense the antimicrobial concentrate;

mixing the antimicrobial concentrate with water to form antimicrobial liquid and circulating the antimicrobial liquid over the exterior surfaces and

-19-

through the interior channels of the device (E);  
draining the antimicrobial liquid; and,  
rinsing the device (E).

9. The method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) as set forth in claim 8 further comprising:

monitoring a flow rate of water passing through the microbe removal filter (54) to monitor the condition of the filter.

10. The method of cleaning and microbially decontaminating the exterior surfaces and interior channels of a medical device (E) as set forth in either claim 8 or 9 wherein the antimicrobial concentrate mixing step comprises:

5 opening second and third compartments (A2,A3) of the multi-compartment container (A) together so that antimicrobial concentrate ingredients in the second and third compartments mix together and react in the water to  
10 form a peracetic acid.

1/3

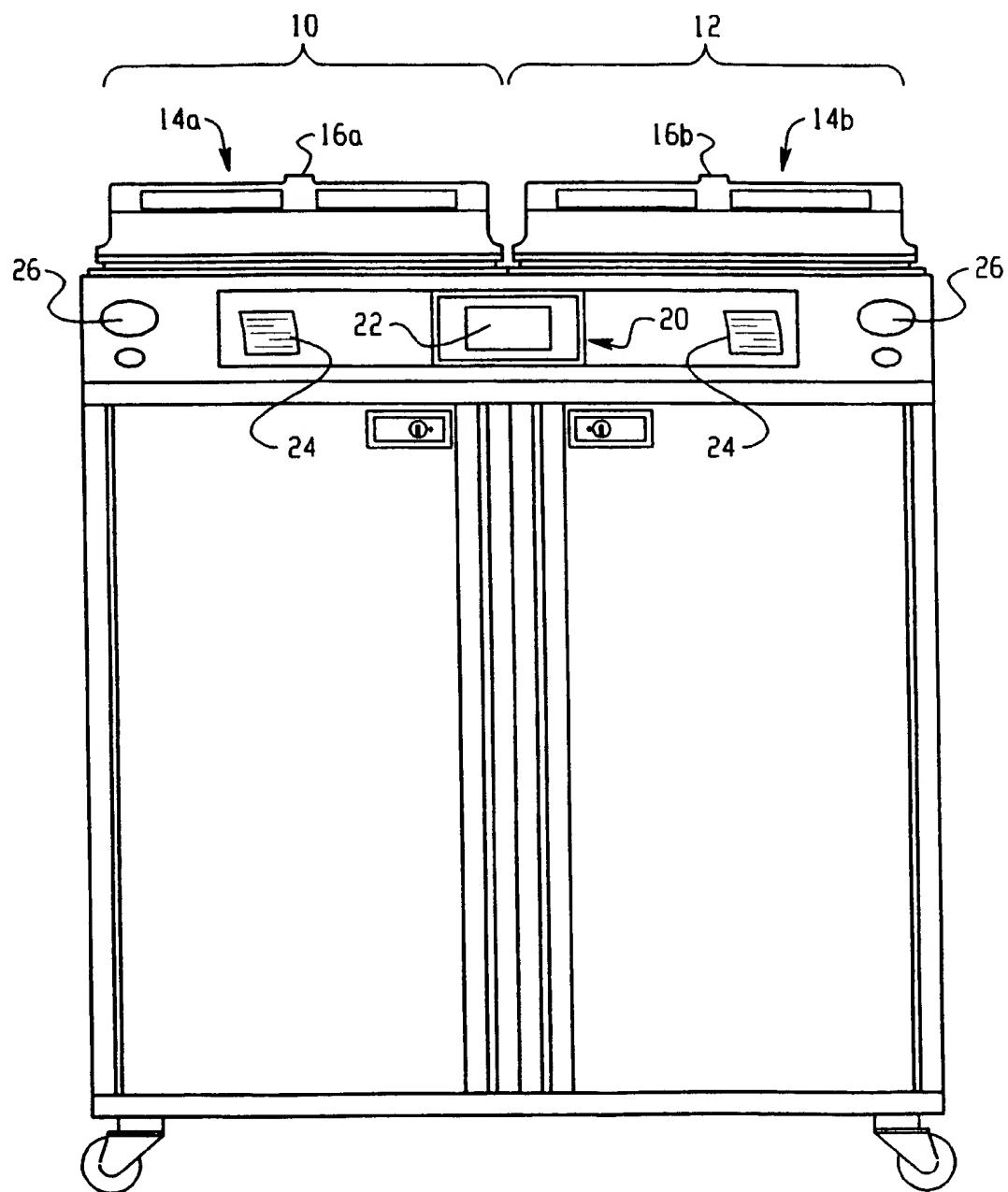
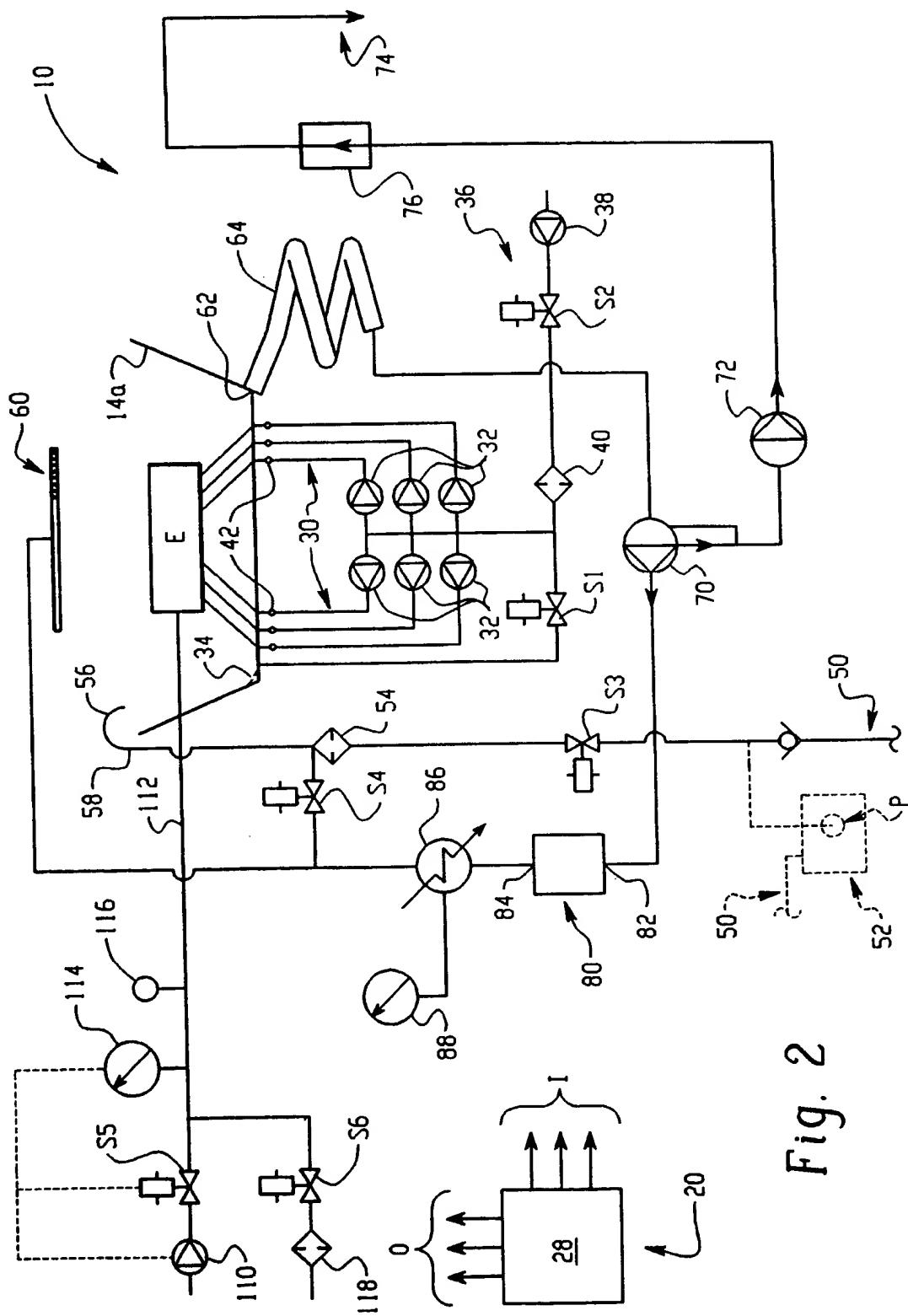
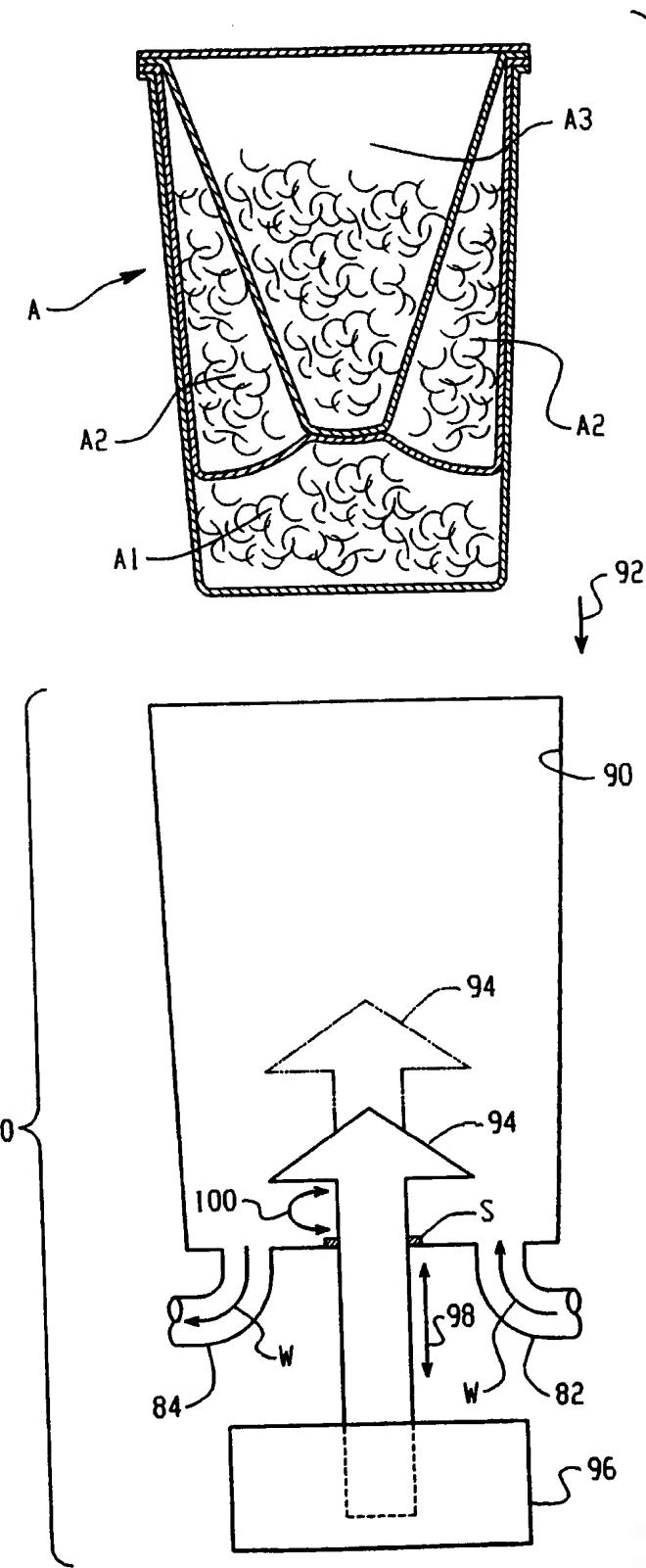


Fig. 1



3/3

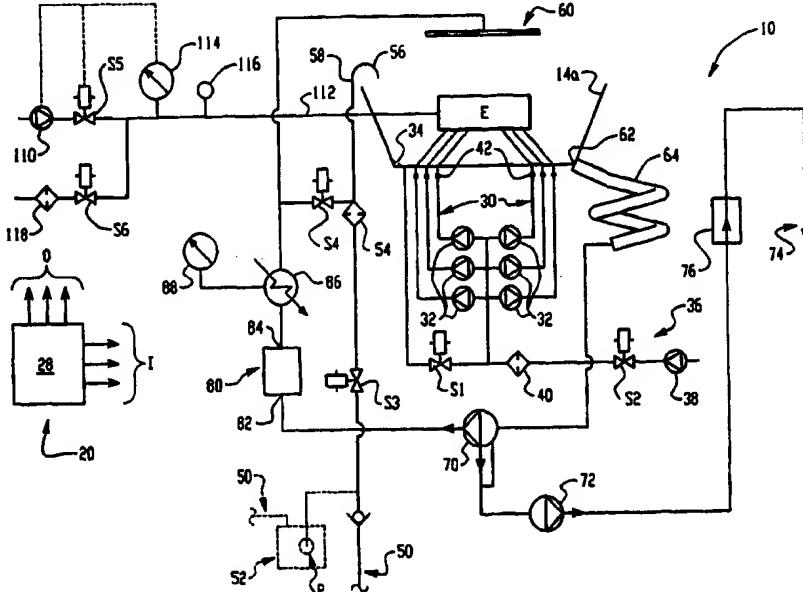


PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61L 2/00, A61B 1/12</b>		A3	(11) International Publication Number: <b>WO 98/58682</b>
			(43) International Publication Date: 30 December 1998 (30.12.98)
<p>(21) International Application Number: PCT/US98/13001</p> <p>(22) International Filing Date: 23 June 1998 (23.06.98)</p> <p>(30) Priority Data: 08/882,466 25 June 1997 (25.06.97) US</p> <p>(71) Applicant: STERIS CORPORATION [US/US]; 5960 Heisley Road, Mentor, OH 44060 (US).</p> <p>(72) Inventor: MALCHESKY, Paul, S.; 239 Barrington Ridge, Painesville Twp., OH 44077 (US).</p> <p>(74) Agent: KOCOVSKY, Thomas, E., Jr.; Fay, Sharpe, Beall, Pagan, Minnich &amp; McKee, Suite 700, 1100 Superior Avenue, Cleveland, OH 44114-2518 (US).</p>		<p>(81) Designated States: AU, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 14 May 1999 (14.05.99)</p>	
<p>(54) Title: APPARATUS AND METHOD FOR STERILIZING MEDICAL DEVICES</p> <p>(57) Abstract</p> <p>A decontamination apparatus for medical devices includes a decontamination basin (14a, 14b) with a selectively opened and closed cover member (16a, 16b) to provide selective access to the basin (14a, 14b). A mixing chamber assembly (80) selectively dispenses detergent concentrate and decontaminant concentrate into a liquid to form a liquid cleaning solution or a liquid decontaminant solution, respectively. A source of decontaminated rinse liquid, such as a microbe removal filter (54), is in selective fluid communication with the basin (14a, 14b). A source of anti-microbial liquid is in selective fluid communication with the microbe removal filter (54) and rinse liquid flow paths (58) between the microbe removal filter and the basin for decontaminating the filter (54) and the rinse lines (58). Each channel of a medical device (E) being decontaminated is connected to a channel flush line (30) and a channel pump (32) for flushing the channels of the device (E). A pressure sensor (42) is in communication with each flush line (30) to sense a blockage in the channels of the medical device (E). The channel pumps (32) pump liquid or decontaminated air through the device channels. A leak test system is also provided for testing the integrity of an outer sheath of a medical device (E) such as an endoscope.</p> 			

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/13001

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 6 A61L2/00 A61B1/12

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61L A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 439 654 A (KOCHTE WERNER W) 8 August 1995 see claims see figures 3-6 ---	1-10
Y	EP 0 709 056 A (FUJINON MEDICAL HOLLAND B V) 1 May 1996 see claims see column 6, line 51 - column 7, line 10 see figure 3 see column 3, line 44 - column 4, line 5 ---	1-10
A	US 5 279 799 A (MOSER HANSRUEDI) 18 January 1994 see claims see figure 1 ---	1-4,6-9 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

10 March 1999

24/03/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Thornton, S

**INTERNATIONAL SEARCH REPORT**

International Application No

PCT/US 98/13001

**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 494 637 A (BARLOW DAVID E) 27 February 1996 see claims see figures 1-8 ---	1-4, 6-9
A	EP 0 232 170 A (INNOVATIVE MEDICAL TECHNOLOG) 12 August 1987 see claims see figure 2 ---	1-5, 8
A	US 5 217 698 A (BEISWENGER JOHN L ET AL) 8 June 1993 see claims see figure 5 ---	1-3, 5, 8, 10
A	US 5 225 160 A (SANFORD BILL R ET AL) 6 July 1993 see claims see figures 1,2 ---	1-3, 6, 8
A	US 5 494 530 A (GRAF MARCEL) 27 February 1996 see claims see figure 2 -----	1-4, 6, 8

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

International Application No

PCT/US 98/13001

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5439654	A 08-08-1995	AU 681296 B AU 2695395 A CA 2182607 A EP 0766571 A JP 2798507 B JP 9504983 T WO 9600092 A		21-08-1997 19-01-1996 04-01-1996 09-04-1997 17-09-1998 20-05-1997 04-01-1996
EP 0709056	A 01-05-1996	NL 9401788 A		03-06-1996
US 5279799	A 18-01-1994	CH 679447 A AT 126032 T DE 59106211 D DK 483059 T EP 0483059 A ES 2075404 T JP 7000936 A		28-02-1992 15-08-1995 14-09-1995 16-10-1995 29-04-1992 01-10-1995 06-01-1995
US 5494637	A 27-02-1996	JP 7051226 A		28-02-1995
EP 0232170	A 12-08-1987	US 4731222 A AT 63222 T CA 1273774 A GR 3001926 T JP 1745511 C JP 4030865 B JP 62186860 A US 5391360 A US 5374394 A US 5407685 A US 5350563 A US 4892706 A US 5037623 A US 5552115 A US 5077008 A US 5116575 A US 5091343 A US 5217698 A US 5225160 A US 5209909 A		15-03-1988 15-05-1991 11-09-1990 23-11-1992 25-03-1993 22-05-1992 15-08-1987 21-02-1995 20-12-1994 18-04-1995 27-09-1994 09-01-1990 06-08-1991 03-09-1996 31-12-1991 26-05-1992 25-02-1992 08-06-1993 06-07-1993 11-05-1993
US 5217698	A 08-06-1993	US 5037623 A US 4731222 A AT 138580 T CA 2058671 A DE 69211048 D DE 69211048 T DK 507461 T EP 0507461 A ES 2087446 T GR 3020259 T JP 1936220 C JP 5092032 A JP 6073540 B US 5391360 A US 5374394 A US 5407685 A US 5350563 A		06-08-1991 15-03-1988 15-06-1996 06-10-1992 04-07-1996 07-11-1996 14-10-1996 07-10-1992 16-07-1996 30-09-1996 26-05-1995 16-04-1993 21-09-1994 21-02-1995 20-12-1994 18-04-1995 27-09-1994

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/13001

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5217698	A	US 5552115 A	03-09-1996
		US 5225160 A	06-07-1993
		US 5077008 A	31-12-1991
		US 5091343 A	25-02-1992
		CA 1320030 A	13-07-1993
		DE 68911339 D	27-01-1994
		DE 68911339 T	07-04-1994
		EP 0332310 A	13-09-1989
		ES 2047109 T	16-02-1994
		HK 183796 A	11-10-1996
		JP 1274765 A	02-11-1989
		JP 1852815 C	21-06-1994
		US 5116575 A	26-05-1992
		AT 63222 T	15-05-1991
		CA 1273774 A	11-09-1990
		EP 0232170 A	12-08-1987
		GR 3001926 T	23-11-1992
		JP 1745511 C	25-03-1993
		JP 4030865 B	22-05-1992
		JP 62186860 A	15-08-1987
		US 4892706 A	09-01-1991
		US 5209909 A	11-05-1993
-----	-----	-----	-----
US 5225160	A 06-07-1993	US 5037623 A	06-08-1991
		US 5217698 A	08-06-1993
		US 4731222 A	15-03-1988
		US 5391360 A	21-02-1995
		US 5374394 A	20-12-1994
		US 5407685 A	18-04-1995
		US 5350563 A	27-09-1994
		US 5552115 A	03-09-1996
		US 5077008 A	31-12-1991
		US 5091343 A	25-02-1993
		CA 1320030 A	13-07-1993
		DE 68911339 D	27-01-1994
		DE 68911339 T	07-04-1994
		EP 0332310 A	13-09-1989
		ES 2047109 T	16-02-1994
		HK 183796 A	11-10-1996
		JP 1274765 A	02-11-1989
		JP 1852815 C	21-06-1994
		US 5116575 A	26-05-1992
		AT 107864 T	15-07-1994
		CA 2012862 A,C	09-11-1990
		DE 69010273 D	04-08-1994
		DE 69010273 T	17-11-1994
		DK 397352 T	31-10-1994
		EP 0397352 A	14-11-1990
		ES 2057391 T	16-10-1994
		HK 183596 A	11-10-1996
		JP 1766177 C	11-06-1993
		JP 3094760 A	19-04-1991
		JP 4055711 B	04-09-1992
		AT 138580 T	15-06-1996
		CA 2058671 A	06-10-1992
		DE 69211048 D	04-07-1996
		DE 69211048 T	07-11-1996
		DK 507461 T	14-10-1996

# INTERNATIONAL SEARCH REPORT

## Information on patent family members

Int	tional Application No
PCT/US 98/13001	

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5225160	A	EP	0507461 A	07-10-1992
		ES	2087446 T	16-07-1996
		GR	3020259 T	30-09-1996
		JP	1936220 C	26-05-1995
		JP	5092032 A	16-04-1993
		JP	6073540 B	21-09-1994
		AT	63222 T	15-05-1991
		CA	1273774 A	11-09-1990
		EP	0232170 A	12-08-1987
		GR	3001926 T	23-11-1992
		JP	1745511 C	25-03-1993
		JP	4030865 B	22-05-1992
		JP	62186860 A	15-08-1987
		US	4892706 A	09-01-1991
		US	5209909 A	11-05-1993
US 5494530	A	27-02-1996	EP	0603563 A
			FI	935438 A
				29-06-1994
				05-06-1994